UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

FRANCES MOODY, Plaintiff, v. ALLERGAN USA, INC., Defendant.	:	Civil Action No. 1:16-cv-901

REPLY MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT ALLERGAN USA, INC.'S MOTION TO DISMISS PLAINTIFF'S VERIFIED COMPLAINT FOR FAILURE TO STATE A CLAIM UPON WHICH RELIEF MAY BE GRANTED

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ON THE BRIEF:

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INTRODUCTION

Plaintiff Frances Moody alleges that the LAP-BAND® obesity device implanted in her was "unsafe." The FDA determined that LAP-BAND® was safe when it granted pre-market approval ("PMA") after a rigorous review process. Federal preemption bars Plaintiff's claims against device manufacturer Allergan. The Medical Device Amendments of 1976 (MDA) contain an express preemption provision. Plaintiff's state-law claims that the LAP-BAND® System was defective are expressly preempted by the MDA because those claims would impose requirements "different from, or in addition to" the specific federal requirements imposed on that medical device via the PMA. *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

In her opposition, Plaintiff has conceded that six of her eight causes of action are preempted, arguing only that Defendant's motion should be denied "as to Plaintiff's second and eight[h] causes of action." (Doc. #9, p.9 of 11) Generally, a "litigant who fails to press a point by supporting it with pertinent authority, or by showing why it is sound despite a lack of supporting authority or in the face of contrary authority, forfeits the point. The court will not do his research for him." *Phillips v. Hillcrest Med. Ctr.*, 244 F.3d 790, 800 n. 10 (10th Cir.2001) (internal quotation marks omitted). Plaintiff has not come forward with legal authority on her design defect, failure to warn and breach of warranty causes of action, and therefore they must be dismissed.

POINT I

THE MANUFACTURING DEFECT CAUSE OF ACTION MUST BE DISMISSED

Despite what Plaintiff states in Opposition (Doc. #9, p. 2 of 11), both the Second and Eighth Causes of Action are expressly preempted and not sufficiently pled with supporting facts. As is clear from Allergan's initial motion papers, Plaintiff's claims fail to state a claim for relief

pursuant to *Fed. R. Civ. P. 12(b)(6).* Ms. Moody's allegations are simply not supported factually. Conclusions are not sufficient to raise a right to relief above the speculative level. In Opposition, Plaintiff argues that they are, citing out-of-date case law suggesting that facts are not required to support allegations in a complaint. (Doc. #9, pp.1-2 of 11) But *Conley v. Gibson*, 355 U.S. 41 (1957) was decided 60 years ago and no longer reflects the federal pleading standard. The United States Supreme Court cases cited by Allergan in its initial motion papers govern. (Doc. #3-4, pp.5-6 of 32) A complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009).

Ms. Moody has not pled sufficient factual content to allow "the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* With regard to her Second Cause of Action entitled Strict Products Liability (Manufacturing Defect), Ms. Moody vaguely asserts that the LAP-BAND® was "defective in its manufacture when it left the hands of Defendant in that it deviated from product specifications, ..." (Exhibit A, ¶ 36) That is just a description or definition of a manufacturing defect, not a factual allegation worthy of the presumption of truth. The "tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678 (citing *Twombly* at 555).

Under New York law, to state a manufacturing defect claim under either negligence or strict liability, the plaintiff must show that the specific product unit was defective as a result of

some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction, and that the defect was the cause of plaintiff's injury. *Horowitz v. Stryker Corp.*, 613 F.Supp.2d 271, 283 (E.D.N.Y.2009) (citing *Colon v. BIC USA, Inc.*, 199 F.Supp.2d 53, 85 (S.D.N.Y.2001)). Ms. Moody has not made such a showing. Her vague, conclusory allegations lack a factual basis that would suggest her claims of manufacturing defect are more than mere conjecture. "The plausibility standard ... asks for more than a sheer possibility that a defendant has acted unlawfully." *Iqbal* at 678 (citing *Twombly* at 556). By failing to allege any facts surrounding the defectiveness of the device implanted in her or a plausible theory for how the device was manufactured improperly, Plaintiff does not give Allergan any notice of the basis for the manufacturing defect claim. "[O]nly a complaint that states a plausible claim for relief survives a motion to dismiss." *Iqbal* at 679. Consequently, the manufacturing defect claims asserted in the Second Cause of Action must be dismissed for failure to state a claim under *Fed. R. Civ. P.* 12(b)(6).

Plaintiff not only begins her Opposition on the wrong foot by citing and relying upon the outdated *Conley v. Gibson* standard but also compounds it by citing a motion for summary judgment standard in a motion to dismiss case. Ms. Moody cites *McArdle v. Navistar Int'l*, 293 A.D.2d 931, 932-33 (3rd Dep't 2002) for the proposition that a defendant may show that a manufacturing defect claim should be dismissed by "submitting proof" that the product was built to specifications and was thoroughly examined and approved prior to shipment. (Doc. #9, p.4 of 11) But *McArdle* was a decision rendered at the summary judgment stage. The decision noted that in order to succeed on a manufacturing defect claim, a plaintiff must establish that the product was not built to specifications or that it deviated from such specifications. *McArdle* at 932. Only then, on "a motion for summary judgment, a defendant seeking dismissal of a strict

products liability claim based on a manufacturing defect must submit admissible proof establishing, as a matter of law, that the product was not defective." *Id.* Ms. Moody has only alleged, not established, that the product was not built to specifications, so the defendant need not come forward with proofs establishing that it *was* built to specifications. Plaintiff has completely missed this critical issue, apparently not recognizing the distinction in this case at the motion to dismiss stage.

Plaintiff then tries to explain why her Second Cause of Action is not preempted, citing *Gelber v. Stryker Corp.*, 788 F. Supp.2d 145, 166 (S.D.N.Y. 2011) for the proposition that defective manufacturing claims based upon a violation of referenced CGMP (current good manufacturing practices) requirements are not preempted. But that 2011 decision was influenced by its particular facts. The Gelbers specifically alleged that the medical device was defective because it was manufactured with "manufacturing residuals" that exceeded Strykers' internal acceptance criteria, rendering the device "adulterated." *Id.* at 155. The Gelbers also alleged that the manufacturing of the device was not in conformity with CGMP requirements, and cited both a warning letter sent by the FDA to Stryker and a subsequent voluntary recall of the medical device. With this evidence set forth in the pleading, the district court refused to dismiss the manufacturing defect claim. "It is certainly plausible that by violating internal acceptance criteria, this conduct also violated manufacturing specifications set forth in the premarket approval application." *Id.* at 157.

Gelber is distinguishable factually from the case at bar. Ms. Moody never specifies what the problem with her subject device was. That "it deviated from product specifications" does not explain how or why. Her pleading lacks facts like the "excessive manufacturing residue" which allegedly led to a wear scar on the implant surface and breaks in the lubrication layer, as stated in

the *Gelber* pleading. *Id.* at 157. Ms. Moody's pleading doesn't even allege, much less set forth facts, suggesting an adulterated product or any FDA warning letter or recall. Without these facts, there is no basis for this Court to follow *Gelber* by allowing the instant case to go forward with allegations of only vague deviations from unstated specifications of a PMA that is never mentioned.

Federal courts in New York have held that pleadings that allege only CGMP violations without more are not sufficient to support a "parallel" manufacturing defect claim, and are preempted. For example, in *Ilarraza v. Medtronic, Inc.*, 677 F.Supp.2d 582, 588 (E.D.N.Y. 2009), the district court ruled that a parallel claim was not stated "because no regulation relied upon refers specifically to the medical device at issue here. Instead, each regulation cited is nothing more than a general statement of a CGMP." CGMP "regulations are purposefully broad so as to apply to a broad range of medical devices." *Id.* They are "simply too generic, standing alone, to serve as the basis for plaintiff's manufacturing defect claims." *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1157 (D. Minn. 2009). The *Ilarraza* court explained why relying upon CGMPs was faulty and subject to express preemption:

> The intentionally vague and open-ended nature of the regulations relied upon is the precise reason why they cannot serve as the basis for a parallel claim. Since these regulations are open to a particular manufacturer's interpretation, allowing them to serve as a basis for a claim would lead to differing safety requirements that might emanate from various lawsuits. This would necessarily result in the imposition of standards that are "different from, or in addition to" those imposed by the MDA - precisely the result that the MDA preemption provision seeks to prevent.

Ilarraza, 677 F.Supp.2d at 588. "Accordingly, where, as here, a plaintiff relies on nothing more than CGMP's in support of a parallel cause of action, preemption bars the claim." *Id.*

Ms. Moody's claim is similarly preempted because she cites only CGMP's in her Complaint, not any violations of specific requirements set forth in the PMA. She also fails to link the alleged violations to her purported injuries. Similar circumstances in other cases have led federal courts in New York to dismiss manufacturing defect cases due to preemption. *See, e.g., Pearsall v. Medtronics, Inc.*, 147 F. Supp. 3d 188, 194 (E.D.N.Y. 2015) ("The CGMPs are guidelines that do not create a federal requirement, and a claim based on alleged failure to comply with the guidelines fails to plead a violation of a federal requirement. To permit a claim that mandates compliance with such 'vague' standards effectively imposes 'different, or additional' requirements, and is preempted."); *Horowitz v. Stryker Corp.*, 613 F.Supp.2d 271, 284 (E.D.N.Y.2009) ("Without more specific allegations explaining how defendants' manufacturing process was in violation of federal requirements so that the device was defective, plaintiff's claim falls directly within the MDA's preemption provision."); *Burkett v. Smith & Nephew, Inc.*, 2014 U.S. Dist. LEXIS 43995, *17 (E.D.N.Y. 2014) ("Accordingly, Burkett's manufacturing defect claim is preempted by the MDA; therefore, it is dismissed."). As in *Horowitz, supra*, at 283, Ms. Moody's "generic allegations of a defective manufacturing claim ... do not demonstrate that they are based on defendants' violation of federal regulations." Therefore her manufacturing defect claim is preempted.

POINT II

PLAINTIFF'S DECEPTIVE PRACTICES ACT CLAIM MUST BE DISMISSED

In her Eighth Cause of Action, Plaintiff alleges a violation of the New York Deceptive Trade Practices Act (NYDTPA) but fails to show that an act, practice, or advertisement was consumer-oriented, and fails to identify a specific advertisement upon which she relied. Further, she fails to properly allege causation by stating she saw any of the alleged deceptive statements,

much less relied upon any. Finally, her allegation that she would not have purchased the LAP-BAND® absent Allergan's deceptive practices is not sufficient to state an injury under New York law. For all of these reasons, her NYDTPA claim must be dismissed.

Although this Count rambles for 21 paragraphs, Plaintiff never actually states that she read or heard of any of Allergan's alleged deceptive statements. "To properly allege causation, a plaintiff must state in his complaint that he has seen the misleading statements of which he complains before he came into possession of the products he purchased." *Goldemberg v. Johnson & Johnson*, 8 F.Supp.3d 467, 480 (S.D.N.Y. 2014) citing *Gale v. Int'l Bus. Machs. Corp.*, 9 A.D.3d 446, 447, 781 N.Y.S.2d 45 (2d Dep't 2004). Ms. Moody fails to identify any specific advertisement or public pronouncement upon which she relied. *See* N.Y. Gen. Bus. Law § 350. She only generically alleges, "These representations were made in uniform promotional materials." (Verified Complaint, ¶ 104) No such materials were attached to her pleading and the specific statements which are allegedly objectionable remain unclear. Nor has she shown actual injury caused by Defendant's statements, another element of the cause of action. Ms. Moody has alleged that she would not have purchased the LAP-BAND® had Allergan not engaged in such deceptive conduct. (*Id.* at ¶ 93) However, "the New York Court of Appeals has rejected the idea that 'consumers who buy a product that they would not have purchased, absent a manufacturer's deceptive commercial practices, have suffered an injury under General Business Law § 349'." *Goldemberg* at 480-81 quoting *Small v. Lorillard Tobacco Co.*, 94 N.Y.2d 43, 56, 698 N.Y.S.2d 615, 720 N.E.2d 892 (1999).

Not only does Ms. Moody fail to plead the necessary elements of New York General Business Law §§ 349 and 350 violations, she fails to include sufficient factual allegations to raise a right of relief above the speculative level. *See Twombly* and *Iqbal*. She gives only flat

assertions and conclusory statements in her pleading, and her Opposition fails to discuss any facts specific to Allergan or its product. It is all boilerplate. At best, this Eighth Cause of Action contains only a formulaic recitation of the elements discussed in the Deceptive Trade Practice Act. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice" to state plausible claims. *Iqbal*, 556 U.S. at 678.

Finally, Plaintiff misapprehends *Goldemberg* for the proposition that New York General Business Law §§ 349-350 can never be preempted by federal law. That is simply untrue. *Goldemberg* involves cosmetics, not medical devices. The FDCA governs both, along with drugs. The Medical Device Amendments of 1976 contain an express preemption provision, specifically barring common law claims against pre-market approved devices. Ms. Moody completely misses this distinction, even though the paragraph she cites from the case in her Opposition (Doc. #9, p. 9 of 11) specifically refers to a code section dealing only with cosmetics: "Accordingly, Plaintiff's claims are not preempted by 21 U.S.C. § 379s(a), and the Court declines to dismiss the instant action on that basis." *Goldemberg*, 8 F.Supp.3d at 476. That code section specifically refers to "cosmetics," not medical devices. Ms. Moody improperly extrapolates from the cosmetics context to conclude that **all** misleading or deceptive claims are outside the scope of preemption. That is incorrect, as federal cases in New York have held that the Medical Device Amendments' express preemption clause bars claims alleging deceptive practices related to devices. *See e.g., Horowitz, supra*, 613 F.Supp. at 288 ("using the NYGBL to attack the [medical device]'s FDA-approved label would run afoul of the MDA's preemption provision. Accordingly, plaintiff's claims for violations under the NYGBL are dismissed."). Thus, Ms. Moody's statement that "case law does not exist" (Doc. #9, p. 9 of 11) regarding the preemption of deceptive trade practices under NYGBL is incorrect.

CONCLUSION

For the foregoing reasons, Allergan's motion to dismiss should be granted in its entirety, with prejudice.

DATED: February 21, 2017

Respectfully submitted,

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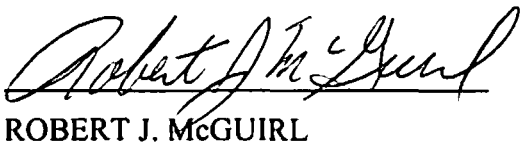

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